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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of:

Applicant : William J. Schmidt
Serial No. : 09/385,405
Filed : August 30, 1999
For : METHOD FOR THE PURIFICATION AND RECOVERY OF WASTE GELATIN
Examiner : R. Popovics
Art Unit : 1723
Attorney Docket No. : 671.1.002 CIP-3

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I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON D.C. 20231
ON August 10, 2001
NAME Jill S. Garretson
SIGNATURE *Jill S. Garretson*

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

August 10, 2001

DECLARATION

Dear Sir:

I, William J. Schmidt, declare and say as follows:

1. I am the sole inventor of the subject matter of the present application.

Furthermore, I am fully familiar with Schmidt, U.S. Patent No. 5,288,408 (hereinafter "the '408 Patent"), cited as a reference against the claims of the pending application, as I am one of the inventors of the '408 Patent.

2. I submit this Declaration and supporting documentation in support of the patentability of the claims of the pending application.

3. The '408 Patent discloses process technology for recovering gelatin and glycerin from a waste stream containing the same. The waste stream is dissolved in a solvent (e.g. deionized water) at a temperature of from 60 to 70°C and then diluted with deionized water to form an aqueous solution of gelatin and glycerin dispersed within the remaining oil and residual active-ingredient components ('408 Patent, column 3, lines 40-56).

4. The lower aqueous phase containing gelatin and glycerin is separated from the upper phase which typically contains lubricating or coating oils (e.g. mineral oil), active ingredients, coloring agents and preservatives (column 4, lines 9-13).

5. The lower phase (i.e. the aqueous phase) is hot filtered by the use of a plate filter, coated plate filter nutche filters or cartridge filters to remove any remaining trails of oil or other contaminants (column 4, lines 22-28) to form a filtrate.

6. The filtrate may then be concentrated by removing a portion of the water through the use of a vacuum distillation process (column 4, lines 32-63).

7. From the time of filing (October 26, 1992) of the patent application which led to the '408 Patent, I have personally observed that the process disclosed in the '408 Patent does not perform on a commercially acceptable scale when one or more of the

specific contaminants including oils with hydrophilic functioning groups (e.g. vitamin E acetate), aromatic oils such as fish oil and garlic oil, and suspended or particulate colorants such as titanium dioxide are present in the waste stream.

8. The present invention sought to improve upon the technology disclosed in the '408 Patent and was developed in response to commercial market criteria and the needs expressed by principal users of gelatin for the manufacture of soft gelatin capsules. In this regard, it was observed that a significant portion of waste gelatin produced commercially, especially in the soft gelatin capsule market contained material amounts of oils with hydrophilic functional groups, aromatic oils, and/or suspended particles.

9. The following tests are submitted to demonstrate the advantages of the present invention over what is fairly disclosed in the '408 Patent and were performed, coordinated and/or observed by me.

10. On or about December, 1998, the following test was performed at General Nutrition Products in Greenville, South Carolina. The test procedures and results are shown in Exhibit A herein. A waste gelatin stream containing gelatin, glycerin and vitamin E acetate (an oil with hydrophilic function groups) at a flow rate of 200 liters per minute at 50°C was treated in accordance with the '408 Patent by subjecting the aqueous phase, after separation from the non-aqueous phase, to treatment with a 10-μ polypropylene cartridge filter until a total of 140 kilograms of waste gelatin was treated. The resulting filtrate was then concentrated using ultra-filtration to obtain a

concentrated sample for analysis. Ultra-filtration was used for concentration because it was ~~considered~~ a more effective process for concentrating (i.e. dewatering) the filtrate than vacuum distillation as specifically disclosed in the '408 Patent.

11. The filtrate produced in accordance with paragraph 10 herein was
5 observed to have a milky white appearance due to the presence of an unacceptable amount of residual emulsified oil. The resulting filtrate was deemed unsuitable for commercial scale recycling of gelatin.

12. On or about May, 2000, the following test was performed at Intergel, Division of IVC Industries in Irvington, New Jersey. The test procedures and results are
10 shown in Exhibit B herein. A waste gelatin stream containing gelatin, glycerin and vitamin E acetate (an oil with hydrophilic function groups) at a flow rate of 200 liters per minute at 50°C was treated by subjecting the aqueous phase, after separation from the non-aqueous phase, to treatment with a 10- μ , polypropylene cartridge filter to produce a first filtrate. The first filtrate was then treated with a 0.65- μ tangential flow microfilter
15 until a total of 145 kilograms of waste gelatin was treated. The resulting filtrate was then concentrated using ultra-filtration to obtain a concentrated sample for analysis.

13. The filtrate produced in accordance with Paragraph 12 herein was observed to have a clear, amber appearance typically associated with previous unprocessed gelatin. The microfiltration step employed in accordance with the present
20 invention surprisingly eliminated residual emulsified oils to the extent that they were essentially undetectable in the resulting filtrate.

14. Soft gelatin capsules were successfully manufactured from the recovered gelatin product produced in accordance with Paragraph 12. In addition, a 3 month accelerated stability test was performed on the resulting capsules as compared with a control containing no recycled gelatin. The results showed no change in physical appearance compared to the control, no change in fill assay compared to the control, no change in microbiological parameters compared to the control, no change in dissolution profile compared to the control, a capsule strength and a seal strength equal to or exceeding the control, and adhesive properties equivalent to or better than the control (See Exhibit B).

15. On or about April, 1999 a series of tests similar to that described in Paragraphs 12-14 were performed at Pall Filtron Corporation, witnessed by representatives of General Nutrition Products and Intergel, with the exception that a 0.45- μ tangential flow microfilter was used to treat the waste gelatin instead of a 0.65- μ tangential flow microfilter. The results were very similar to that described in Paragraphs 12-14 herein, i.e the waste gelatin had a clear, amber appearance with essentially no detectable emulsified oils.

16. In October, 2000, large scale trials were performed at Nutricia Manufacturing USA, Inc. on behalf of Millipore Corporation (a licensee to Applicant herein) on a waste gelatin stream similar to that described in Paragraphs 10-14 to determine if a smaller pore cartridge filter in accordance with the '408 Patent could be effectively used to remove the residual emulsified oils. The test procedures and results are shown in Exhibit C herein. In this regard, a 1- μ and 0.3- μ cartridge filter were

tested. The 1- μ cartridge filter did not remove the residual oils. The 0.3- μ cartridge filter resulted in a reduced a unacceptable throughput and eventual oil breakthrough. Millipore's conclusion regarding this test was:

"Due to low filtrate throughput and early
breakthrough, the number of cartridges required for this
application is very large and thus, the process becomes
unrealistic."

17. In or about February, 2001, laboratory scale tests (900 ml batch size) were performed similar to the tests described in Paragraph 16 using a 0.5- μ cartridge filter at a reduced back pressure (i.e. 10 psig instead of 15 psig). The results showed very low throughput and oil breakthrough when the back pressure was increased. A 1- μ cartridge filter was used successfully on a laboratory scale at 10 psig but resulted in oil breakthrough when the batch size was increased from 900 ml to 120 l. It was thus clearly demonstrated by the test set forth in paragraphs 16 and 17, that cartridge filtration, as described in the '408 Patent, even with a smaller pore size, does not achieve the removal of contaminants achieved by the use of tangential flow microfiltration as taught by the present invention. I consider this discovery to be surprising and unobvious from the '408 Patent disclosure.

18. In or about August, 2000 processes similar to that described in Paragraphs 10 and 12 respectively were conducted (See Exhibit D herein) on a waste gelatin stream containing gelatin, glycerin, and fish oil. In particular, a waste gelatin

stream (400 kg total batch) at a flow rate of 200 liters per minute at 50°C was treated with a 1- μ cartridge filter which resulted in a permeate having a distinct "fishy smell". When the process was carried out under the same conditions using a 1- μ cartridge filter and a 0.65- μ tangential flow microfilter, the permeate was odor free indicating that essentially all of the fish oil had been removed. The test procedures and successful results obtained in accordance with the present invention are shown in Exhibit D herein.

19. A waste stream containing suspended colorants such as titanium dioxide having an average particle size of 0.3- μ would require a cartridge filter having a pore size of about 0.1- μ . However, as discussed in paragraphs 16 and 17 herein, such small pore sizes would reduce the throughput of the waste stream to an extent that the process would be unacceptable on a commercial scale. Coated plate filters of the type described in the '408 Patent which typically have a pore size of 1- μ would allow the suspended particles to pass therethrough. Rosenmund and/or Nutche type filters are much too expensive to be practical for the commercial operation of treating waste streams containing suspended particles.

20. In accordance with the present invention, centrifugation which does not rely on pore size, has been successful in removing suspended particles from a waste gelatin stream containing the same.

21. I am aware that the Office Action states that the claimed invention is obvious in light of the '408 Patent. In addition to the comparative data presented herein, it is my view that the capsule manufacturing industry did not consider it obvious

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to proceed from the technology disclosed in the '408 Patent to the technology claimed in the present application because the differences were not obvious. The industry did not make this transition despite an overwhelming need in the industry to effectively remove contaminants such as oils with hydrophobic functional groups from the waste stream. To further establish the non-obviousness of the claimed invention, I submit herewith a brief summary of the state of the capsule manufacturing from the time of the '408 Patent. In or about 1993, I made presentations and/or demonstrations, of the invention fairly disclosed in the '408 Patent, to soft gelatin capsule manufacturers including Pharmavite, Banner and R.P. Scherer, the latter two being the largest manufacturers of such capsules in the world.

From that time until the present application, no soft gelatin capsule manufacturer to my knowledge, including those highly reputable manufacturers mentioned above, made any advances in the field of waste stream recovery that resemble the present invention, despite their actual knowledge and exposure to the '408 Patent.

22. The nature of the waste gelatin problem addressed by the present invention is of such a magnitude that, if it were obvious to arrive at the present invention from the teachings of the '408 Patent, these leading soft gel manufacturers would have done so. Instead, I am in license negotiations with these companies, further indicating the need and non-obviousness of the present invention over the '408 Patent.

ARK:jsg072601/6711002CIP-3.DEC-WJS

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 3 August 01



William J. Schmidt